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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,724	08/31/2001	Xu Cao	D6106D	2798

7590 12/03/2002

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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,724	CAO ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6, 8, 13-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to method of stimulating bone formation in an individual, classified in class 514, subclass 1.

Group I is comprised of multiple inventions which are the methods drawn to different and distinct interaction inductions (e.g., claim 2), transcription factors (e.g., claim 3), and BMP-responsive genes (e.g. claim 4) which do not render obvious each other and thus are patentably distinct. If Group I is elected, applicants must elect a single invention which is the method drawn to one specific interaction induction, one specific transcription factor, and one specific BMP-responsive gene to which the claims will be restricted.

II. Claim 6, drawn to method of inducing gene(s) encoding bone matrix proteins, classified in class 435, subclass 375.

III. Claim 8, drawn to method of screening for a compound, classified in class 435, subclass 29.

Group III is comprised of multiple inventions which are the methods drawn to different and distinct interaction inductions (e.g., claim 8) which do not render obvious each other and thus are patentably distinct. If Group III is elected, applicants must elect a single invention which is the method drawn to one specific interaction induction to which the claim will be restricted.

IV. Claims 13-17, drawn to method of regulating disease in an individual, classified in class 514, subclass 1.

Group IV is comprised of multiple inventions which are the methods drawn to different and distinct compounds (e.g. claim 15), transcription factors (e.g., claim 16), and diseases that the individual has (e.g. claim 17) which do not render obvious each other and thus are patentably distinct. If Group IV elected, applicants must elect a single invention which is the method drawn to one specific compound, one specific transcription factor, and one specific disease that the individual has to which the claims will be restricted.

Claims 1, 8, and 13 links inventions drawn to the methods drawn to distinct interaction inductions, transcription factors, BMP-responsive gene, type of compound used, and disease the individual has. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 8, or 13. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The multiple inventions of Group I are chemically, biologically, and functionally different distinct from each other and thus one specific invention does not render the others obvious. The interaction inductions are drawn to different and distinct types of interaction induction that are chemically, biologically, and functionally different and distinct from each other and thus methods drawn to the use of these distinct interactions are themselves distinct from each other. The specific transcription factor and BMP-responsive genes are chemically, biologically, and functionally different and distinct from each other and thus methods drawn to the use of these distinct transcription factors and genes themselves are distinct from each other. Therefore, the inventions of this group are capable of supporting separate patents.

The multiple inventions of Group III are chemically, biologically, and functionally different distinct from each other and thus one specific invention does not render the others obvious. The interaction inductions are drawn to different and distinct types of interaction induction that are chemically, biologically, and functionally different and distinct from each other and thus methods drawn to the use of these distinct

interactions are themselves distinct from each other. Therefore, the inventions of this group are capable of supporting separate patents.

The multiple inventions of Group IV are chemically, biologically, and functionally different distinct from each other and thus one specific invention does not render the others obvious. The compounds are drawn to different and distinct compounds that are chemically, biologically, and functionally different and distinct from each other and thus methods drawn to the use of these distinct compounds are themselves distinct from each other. The specific transcription factor and specific disease that the individual has are chemically, biologically, and functionally different and distinct from each other and thus methods drawn to the use of these distinct transcription factors and individuals having a disease themselves are distinct from each other. Therefore, the inventions of this group are capable of supporting separate patents.

Inventions of Groups I-IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-IV comprise steps which are not required for or present in the methods of the other groups: inducing an interaction which produces osteoblast and/or chrondroblast differentiation (Group I),

inducing gene(s) encoding bone matrix proteins (Group II), determining the ability of a compound to inhibit binding of Hoxc-8 to a gene (Group III), and inhibiting the binding of a transcription factor to remove transcriptional repression (Group IV). The end result of the methods are different: stimulating bone formation (Group I), inducing gene(s) encoding bone matrix proteins (Group II), screened compound (Group III), and regulated disease in an individual (Group IV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group IV, with regard to the non-patent literature search because the complete search of each of these groups requires a separate search for the method steps not in common with each other, restriction for examination purposes as indicated is proper.

A telephone call was made to Benjamin Adler on 1/17/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the interests of compact prosecution, the following is noted and must be corrected. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of the Sequence Rules because the application refers to sequences without the use of the correct identifier.

For example, in Figure 4A the specification sets forth sequences without use of the proper identifiers.

Applicants should carefully review the specification to identify and properly label each sequence that is referred to within the specification, including drawings. Sequences in drawings can be identified with a SEQ ID NO: in the Brief Description of the Drawings for the figure or be present in the figure itself. If one or more sequences are referred to in the specification that are not present in the Sequence Listing, then a new Sequence Listing, a new CRF diskette containing the Sequence Listing and a new statement that the two are the same and includes no new matter must be submitted in order to fully comply with the Sequence Rules.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

December 1, 2002